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(73) Proprietor: **BOSTON SCIENTIFIC CORPORATION**
480 Pleasant Street
Watertown, MA 02172(US)

(72) Inventor: **Noddin, Richard A.**
1390 Washington Street
Holliston, MA 01746(US)
Inventor: **Barry, Ralph J., Jr.**
74 Warner Street
Hudson, MA 01749(US)
Inventor: **Madenjian, Arthur R.**
60-F Lionel Avenue
Waltham, MA 02154(US)

(74) Representative: **Bardehle, Heinz, Dipl.-Ing.**
Patent- und Rechtsanwälte
Bardehle-Pagenberg-Dost-Altenburg-Frohwitter-Geissler & Partner
Postfach 86 06 20
D-81633 München (DE)

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Description

BACKGROUND OF THE INVENTION

The invention relates to medical balloons and especially to angioplasty dilatation balloon catheters.

Such balloons are intended to be collapsed to small size about their long supporting devices. In the case, e.g., of angioplasty balloon catheters, the small size is necessary to enable advance of the catheter through narrow and curved blood vessels into the region of stenosis where the balloon is to be inflated. After use, the balloon must be deflated and withdrawn. It is important in such movements not to damage the vessel walls or other delicate tissue of the body.

The process of making such balloons usually starts with an extruded cylindrical tube of a given diameter and wall thickness. The tube, in its amorphous state, is heated to blowing temperature and inflated and drawn longitudinally. Thus a tube of amorphous polyethylene terephthalate can be drawn and expanded to achieve a wall thickness of less than 0.003 cm (.001 inch) in the main body of the balloon with wall thicknesses that increase in the tapered proximal and distal transition regions.

Whereas such balloons have been found to be quite useful, especially when high strength resins are employed to provide correspondingly high pressures of inflation, there have been disadvantages attributable to the thickness of the balloon material in the transition regions.

During folding of the balloon and wrapping it around the catheter shaft to make it small size for insertion, protruding bumps or distortions occur at the ends of the balloon. Because of the thickness of the material at these regions, these distortions can be relatively stiff and sharp and can cause trauma to the arteries or other passages through which the balloon is passed.

One area in which improvement is particularly needed in this regard is that of large diameter, high pressure angioplasty balloon catheters, i.e., balloon catheters in which the diameter of the main body of the balloon, when inflated, is between about 5 to 12 millimeters.

Also, known techniques have made it difficult to achieve balloon catheters for other applications, for instance, balloon catheters that require elongated sleeves to fit tightly over very small catheters.

Furthermore, a method acc. to the first part of claim 1 has become known from EP-A-0 135 990 (E.I. DU PONT).

SUMMARY OF THE INVENTION

The technical **problem** of the invention regarding this prior art is to minimize protruding bumps or distortions during folding of the balloon ad wrapping it around the catheter shaft to make it small size for insertion.

The **solution** to this problem is accomplished by the **characterizing part** of **Claims 1** and **12**, respectively.

The invention provides a separately controlling of the wall thickness in the tapered proximal and distal transition regions of the balloon.

The **remaining Claims** go further in specifying the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

We first briefly describe the drawings.

Figure 1 is a diagramatic view of an extrusion-formed tubular element of a selected resin material being heated and drawn as a step of the present invention. Figure 1a is a diagramatic view of a drawn section of the tubular element. Figure 1b is an alternate view similar to 1a of another form with a more elongated necked-down region than shown in Figure 1a. Figure 1c is a view on a smaller scale showing the entire preform with two necked-down regions separated by a distance L.

Figure 2 is a diagramatic view of the preform of Figure 1c in a position ready to be blown into a balloon. Figure 3 is a view similar to Figure 2 but in cross-section showing the formed balloon. Figure 3a is a cross-section of the wall of the balloon of Figure 3 showing the generally uniform wall thickness achievable along the length of the tube. Figure 4 is a side view of a finished balloon produced according to the invention. Fig. 5 is a similar view of an angioplasty balloon catheter according to the invention. Fig. 6 is a thermal analysis curve of PET resin.

Detailed Description of Preferred Embodiment

Referring to Figure 1, a tube suitable for blowing a medical balloon of 8mm diameter is provided, comprised of a nondistendable resin, Goodyear's Clear Tuf 8006, polyethylene terephthalate, having an outer diameter of 0.17 cm (0.066 inches) and a wall thickness of 0.028 cm 0.011 inches). A portion 10a of the tube, up to line B has been crystallized to render it dimensionally stable under heated conditions. The portion thus stabilized can not be appreciably inflated or drawn. The tube 10 is immersed in a heated bath 12 of glycerine at a drawing temperature selected from the range of about 105 to 130 degrees centigrade, e.g., 120

degrees centigrade. The crystallized region is fully immersed together with a short portion, D_I, e.g., 3 mm, of the amorphous portion 10b of the tube. The portion of the tube out of the bath is gripped by a fixed clamp 14, and the crystallized portion of the tube submerged in the bath is gripped by a moveable clamp 16. After a suitable duration of immersion, to ensure that the resin reaches the temperature of the bath, clamp 16 is moved downwardly a predetermined distance, e.g., 2 mm at a draw rate in the range of about one inch to 0.25 cm (0.1 inch) per minute, e.g., 0.75 cm (0.3 inch) per minute, in the direction of the arrow, causing the heated amorphous portion of the tube to be drawn, the crystallized portion resisting such deformation. Referring to Figure 1a, tube 10, in the region between A and B as shown in Figure 1, is necked-down as a result of such drawing. The degree of necking and thinning of the walls obviously depends upon the conditions of drawing, e.g., the drawing rate, drawing temperature, length of the amorphous portion being drawn and the distance of draw, the values of which for any particular balloon can be determined by ready trial. In the preferred embodiment being described, the tube's outer diameter, OD_d, is necked-down to 0.137 cm (0.054 inch) and the tube is lengthened 2 mm. In the alternative embodiment of Figure 1b in which a longer portion of the amorphous tube has been immersed, the tube is drawn down to a constant diameter sleeve 19.

After the initial necking-down of the tube, the tube is reversed in the bath and the second necked-down portion is formed by the same procedure, at a point spaced along the amorphous tube a distance L, e.g., 1.45 cm (0.57 inch), to provide a section of tube between the necked-down regions which will be drawn and blown in forming the main body of the balloon. This procedure can provide a preform in which the thickness of the wall of the tube in the region of the drawn-down deformation decreases with decrease in diameter.

After the preform is completed, it is submerged in a second bath of glycerine as shown in Figure 2, this time arranged horizontally, and with the tube extending through two stationary constraining elements 18, the crystallized portions of the tube being grasped by clamps 20 and 22. The temperature of bath 12a is regulated to correspond to the desired blowing temperature, selected from the range of about 85 to 115 degrees centigrade, e.g., 90 degrees centigrade. Each constraining element 18 is comprised of a cylindrical portion 18a and a conical portion 18b, the wide ends of the conical portions being opposed to each other, arranged to define the shape of the tapered sections of the balloon.

As shown, the crystallized regions of the tube end at points C and D in the initial setup of Figure 2. After the temperature of the tube has stabilized in bath 12a, the two clamps 20 and 22 are drawn apart, causing the tube to slide through the stationary constraining elements 18 as it is lengthened. Simultaneously, gas pressure is applied to the interior of the tube, causing it to expand. The region, L, of the tube expands without constraint until the molecules of the wall material in the balloon region become stabilized in a biaxially oriented condition. In its final form, the balloon reaches an OD of 8mm and the length between the tapered sections, increases to $L + \Delta L$ = 3.8cm (1.51 inches). The portions of the tube having the preformed tapers also expand until they are constrained to the shape of constraining element 18. The final balloon thickness profile is illustrated in Figure 3a in which the thickness of the balloon t_b is 0.0018 cm (0.0007 inches) and the thickness t_t of the tapered wall is substantially of the same value with variation less than about 0.0003 cm (0.0001 inch). The length of the amorphous region during the blow and draw step increases from L_2 = 2.4 cm (0.94 inch) to $L_2 + \Delta L_2$ = 6.9 cm (2.70 inch).

In another embodiment, in forming the preform, e.g., by drawing more on the defined region, and thus drawing the taper down further, it is possible to achieve in the blown balloon a wall thickness of the transition region that is less than that of the main body of the balloon.

After formation of the balloon, the balloon is cooled, dried, the end portions are cut away, e.g., the portions extending outwardly from the smallest diameter of the necked down region, and the balloon 21 is assembled upon a suitable catheter 23 which has a balloon inflation lumen 25 for inflation of the balloon and a through lumen 27 for receiving a guidewire, see Fig. 5. Radiopaque markers 29 are provided on the catheter at the ends of the main body of the balloon 21. In this manner, a large balloon, e.g., of 8 mm diameter, capable of pressures of, e.g., 8 atmospheres can be obtained, having transition regions that are sufficiently thin to enable very successful dilatation.

A further advantage of the invention is obtained when making the larger balloon sizes for assembly on small catheters, for instance an 8 mm balloon on a 5 French catheter. To form such a balloon, it is advantageous to choose a starting tube of diameter greater than the outer diameter of the catheter on which the balloon is ultimately to be mounted. By use of the drawing steps to form the preform, it is readily possible, in the defined heated regions, to draw the diameter of these regions to a size corresponding to the size of the catheter.

In other embodiments the wall thickness of the tapered section can be increased or decreased

according to the amount of draw performed during fabrication of the preform. In some embodiments the use of constraining elements in the end regions may be omitted and in other embodiments the entire preform may be confined in a mold for determining the final blown shape. The temperature in other embodiments may be outside of the preferred ranges mentioned, provided certain relationships are maintained as described in the summary of the invention, above, with reference to the thermal analysis curve for the respective resin; see the example for the preferred embodiment, Figure 6.

For certain of the broader aspects of the invention, other forming techniques such as molding of a softened tube are possible for preparing the tapered preform.

Claims

1. **Method of forming** an inflatable medical **balloon** (21)
   - including the steps of
   - **providing a tube** (10)
   - of a selected resin
   - of wall thickness and diameter suitable for being formed into a balloon (21) for a balloon catheter device (23),
   - **heating said tube** (10)
   - to blowing temperature
   - and, while heated,
   - **forming said balloon** (21)
   - by **drawing** and **blowing** said tube (10), and
   - **mounting** said balloon (21)
   - to form a balloon catheter device (23),

   characterized in that
   - a **defined region** (10b) of said tube (10)
   - at an end of the portion of said tube (10) from which said balloon (21) is to be formed *(Fig. 1)*
   - is selectively **heated** to drawing temperature and
   - **tension** is applied in opposite directions (14, 16) *(Fig. 1)*
   - to respective ends of said heated region
   - to **draw** said heated region
   - to a smaller diameter and wall thickness (A, B) *(Fig. 1a)* (19) *(Fig.1b)*
   - thereby providing
   - a **tubular preform** *(Fig. 1c)*
   - having, at said end of said portion of tube,
   - a **tapered** relatively **small diameter region**
   - comprised of material
   - that has substantially no crystallization or molecular orientation;
   - the step of **preforming** said tapered end region
   - enabling the corresponding section of said blown balloon *(Fig. 3)* to have a separately controllable thickness profile *(Fig. 3a)*.

2. Method of claim 1,
   characterized in that
   - **two defined regions** (10b) of said tube (10) *(Figs. 1c, 2)* are
   - selectively heated to drawing temperature, and
   - tension is applied in opposite directions to respective ends of said heated region to draw **each** region to a smaller diameter and wall thickness.

3. Method of claim 1 or 2,
   characterized in that
   - said drawing temperature is
   - above the glass transition temperature and
   - below crystallization temperature
   - such that substantially no crystallization or molecular orientation occurs.

4. Method of claim 1 or 2,
   characterized in that
   - said drawing temperature is
   - near or above the melt temperature of said resin and
   - after drawing, said preform is rapidly quenched.

5. Method of claim 1 or 2,
   characterized in that
   - said blowing temperature is
   - approximately the glass transition temperature or above, and
   - substantially below the crystallization temperature of said resin.

6. Method of claim 5,
   characterized in that,
   - for biaxially orienting said balloon (21),
   - said blowing temperature is
   - below the drawing temperature,
   - in the region of the glass transition temperature of said resin.

7. Method of claim 1 or 2,
   characterized in that
   - said resin is
   - amorphous polyethylene terephthalate,
   - said drawing temperature is
   - between about 105 and 130 °C.
   - said blowing temperature is

- between about 85 and 115 °C.

8. Method of claim 1 or 2,
characterized in that
- said drawing to form said preform and
- said step of drawing and blowing said preform
- are so related that
- the wall thickness of the main body of said balloon (21) and
- the wall thickness of a tapered end section of said balloon (21)
- are of substantially equal value.

9. Method of claim 1 or 2,
characterized in that
- said heating of said defined region
- is performed in such a manner
- that the portion of the tube from which the main body of said balloon is to be formed
- is not substantially heated.

10. **Balloon product** made according to the method of claim **1** or **2**.

11. **Balloon product** made according to the method of claim **8**.

12. **Dilatation balloon catheter** for angioplasty
- having:
- an elongated, small diameter **catheter** - (23)
  - adapted to be passed through the vascular system of the body
  - to a point of stenotic occlusion of a blood vessel,
- an inflatable **dilatation balloon** (21)
  - secured about said catheter (23),
  - adapted to be inflated at said point of occlusion
  - to enlarge the blood vessel and relieve the restriction to blood flow, and
  - comprising
  - a **main body section** and
  - at least one **transition section** at one end of said main body section, and
- **means** (25) to **inflate** and **deflate** said balloon (21),

characterized in that
- said **balloon** (21) is
- the product of the process
- of blowing and drawing
- a **preformed tubular member**
- having
- a tapered contour
- in the region corresponding to the transition section of the blown balloon,
- said tapered contour
- having
- a smaller diameter and reduced wall thickness
- than the diameter and wall thickness of said main body section,
- thereby enabling the corresponding sections of the blown balloon
- to have separately controllable thickness profiles *(Fig. 3)*.

13. Dilatation balloon catheter of claim 12,
characterized in that
- the preformed tubular member is
- the product of heating and drawing
- a defined region of an extruded tube (10)
- of originally constant diameter and wall thickness.

14. Dilatation balloon catheter of claim 12,
characterized in that
- the wall thickness of said tapering transition section is
- about the **same** as the wall thickness of the main body of said balloon (21).

15. Dilatation balloon catheter of claim 12,
characterized in that
- the wall thickness of said tapering transition section is
- **less** than the wall thickness of the main body of said balloon (21).

16. Dilatation balloon catheter of claim 12, 13, 14 or 15,
characterized in that
- the main body of said balloon (21) has
- an inflated diameter of 5 mm or larger.

17. Dilatation balloon catheter of claim 12, 13, 14 or 15,
characterized in that
- the resin from which said balloon (21) is formed is
- polyethylene terephthalate.

Patentansprüche

1. Verfahren zur Formung eines aufblasbaren medizinischen Ballons (21) umfassend die Schritte:
Bereitstellung eines Rohres (10) aus einem ausgewählten Harz von einer Wandstärke und einem Durchmesser geeignet zur Formung eines Ballons (21) für eine Ballonkathetervorrichtung (23), Erwärmen des Rohrs auf die Aufblastemperatur und, während des Erwärmens,

Formen des Ballons (21) durch Ziehen und Aufblasen des Rohres (10), und Montieren des Ballons (21), um eine Ballonkathetervorrichtung (23) zu bilden, dadurch **gekennzeichnet,** daß ein definierter Bereich (10b) des Rohres (10) an einem Endabschnitt des Rohres (10), aus dem der Ballon (21) zu formen ist (Fig. 1), selektiv auf Ziehtemperatur erwärmt wird und in entgegengesetzten Richtungen (14, 16) (Fig. 1) auf die jeweiligen Enden des erwärmten Bereiches Zugspannung ausgeübt wird, um den erwärmten Bereich auf einen kleineren Durchmesser und eine kleinere Wandstärke (A, B) (Fig. 1a) (19) (Fig. 1b) zu ziehen und dadurch eine rohrförmige Vorform (Fig. 1c) bereitzustellen, die an dem Ende des Rohrabschnittes einen sich verengenden Bereich verhältnismäßig kleinen Durchmessers aus einem Material besitzt, das im wesentlichen keine Kristallisation oder molekulare Orientierung aufweist, wobei der Schritt des Vorformens des sich verengenden Endabschnittes der entsprechenden Sektion des aufgeblasenen Ballons (Fig. 3) ermöglicht, ein getrennt steuerbares Dickenprofil (Fig. 3a) zu haben.

2. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß zwei definierte Bereiche (10b) des Rohres (10) (Fig. 1c, 2) selektiv auf Ziehtemperatur erwärmt werden, und daß in entgegengesetzten Richtungen auf jeweilige Enden des erwärmten Bereiches Zugspannung ausgeübt wird, um jeden Bereich auf einen kleineren Durchmesser und kleinere Wandstärke zu ziehen.

3. Verfahren nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Ziehtemperatur über der Glasübergangstemperatur und unter der Kristallisationstemperatur liegt, so daß im wesentlichen keine Kristallisation oder molekulare Orientierung entsteht.

4. Verfahren nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Ziehtemperatur nahe oder über der Schmelztemperatur des Harzes ist und nach dem Ziehen die Vorform schnell abgekühlt wird.

5. Verfahren nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Aufblastemperatur ungefähr die Glasübergangstemperatur oder darüber ist, und im wesentlichen unter der Kristallisationstemperatur des Harzes.

6. Verfahren nach Anspruch 5, dadurch gekennzeichnet, daß für biaxiale Orientierung des Ballons (21) die Aufblastemperatur unter der Ziehtemperatur ist, im Bereich der Glasübergangstemperatur des Harzes.

7. Verfahren nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß das Harz amorphes Polyäthylenterephthalat ist, die Ziehtemperatur zwischen etwa 105 und 130 °C und die Aufblastemperatur zwischen etwa 85 und 115 °C liegt.

8. Verfahren nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß das Ziehen zur Formung der Vorform und der Schritt des Ziehens und Aufblasens der Vorform so miteinander in Beziehung stehen, daß die Wandstärke des Hauptkörpers des Ballons (21) und die Wandstärke einer sich verengenden Endsektion des Ballons (21) im wesentlichen den gleichen Wert haben.

9. Verfahren nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Erwärmung des definierten Abschnittes in solcher Weise durchgeführt wird, daß der Abschnitt der Röhre, aus dem der Hauptkörper des Ballons zu formen ist, nicht wesentlich erwärmt wird.

10. Ballon, hergestellt nach dem Verfahren von Anspruch 1 oder 2.

11. Ballon, hergestellt nach dem Verfahren von Anspruch 8.

12. Ballonkatheter zur Dilatation in der Angioplastie, der aufweist einen langgestreckten Katheter (23) von kleinem Durchmesser, der geeignet ist, durch das vaskuläre System des Körpers durchgeführt zu werden an einen Punkt stenotischer Okklusion eines Blutgefäßes, einen aufblasbaren Dilatationsballon (21), der über den Katheter (23) befestigt und dazu bestimmt ist, an dem Okklusionspunkt aufgeblasen zu werden, um das Blutgefäß zu vergrößern und die Beeinträchtigung des Blutflusses zu beheben, und eine Hauptkörpersektion und wenigstens eine Übergangssektion an einem Ende der Hauptkörpersektion sowie Vorrichtungen (25) zum Aufblasen und Ablassen des Ballons (21), dadurch gekennzeichnet, daß der Ballon (21) das Produkt des Verfahrens des Aufblasens und Ziehens eines vorgeformten rohrförmigen Elementes ist, das eine sich verengende Kontur in dem Bereich entsprechend der Übergangssektion des aufgeblasenen Ballons aufweist, wobei die sich verengende Kontur einen kleineren Durchmesser und verringerte Wandstärke im Vergleich zu Durchmesser und Wandstärke der Hauptkörpersektion auf-

weist, wodurch es ermöglicht wird, daß die entsprechenden Sektionen des aufgeblasenen Ballons separat steuerbare Dickenprofile haben (Fig. 3).

13. Ballonkatheter zur Dilatation nach Anspruch 12, dadurch gekennzeichnet, daß das vorgeformte rohrförmige Element das Produkt des Erwärmens und Ziehens eines definierten Bereichs eines extrudierten Rohres (10) ist, das ursprünglich konstanten Durchmesser und konstante Wandstärke hatte.

14. Ballonkatheter zur Dilatation nach Anspruch 12, dadurch gekennzeichnet, daß die Wandstärke der sich verengenden Übergangssektion ungefähr die gleiche ist wie die Wandstärke des Hauptkörpers des Ballons (21).

15. Ballonkatheter zur Dilatation nach Anspruch 12, dadurch gekennzeichnet, daß die Wandstärke der sich verengenden Übergangssektion kleiner ist als die Wandstärke des Hauptkörpers des Ballons (21).

16. Ballonkatheter zur Dilatation nach den Ansprüchen 12, 13, 14 oder 15, dadurch gekennzeichnet, daß der Hauptkörper des Ballons (21) einen aufgeblasenen Durchmesser von 5 mm oder mehr aufweist.

17. Ballonkatheter zur Dilatation nach den Ansprüchen 12, 13, 14 oder 15, dadurch gekennzeichnet, daß das Harz, aus dem der Ballon (21) geformt ist, Polyäthylenterephthalat ist.

Revendications

1. **Procédé pour former** un **ballonnet** médical gonflable (21)
   - comprenant les étapes consistant à
   - **préparer un tube** (10)
   - d'une résine choisie
   - d'une épaisseur de paroi et d'un diamètre propres à être formés en un ballonnet (21) pour un appareil à cathéter à ballonnet (23),
   - **chauffer ce tube** (10)
   - à une température de soufflage
   - et, lorsqu'il est chauffé,
   - **former ledit ballonnet** (21)
   - en **étirant** et en **soufflant** ce tube (10) et
   - **monter** ce ballonnet (21)
   - de manière à former un dispositif à cathéter à ballonnet (23),

   caractérisé en ce que
   - on **chauffe** sélectivement à une température d'étirage
   - une **région prédéfinie** (10b) du tube (10)
   - à une extrémité de la partie de ce tube (10) à partir de laquelle le ballonnet (21) doit être formé (fig. 1) et
   - on applique une **tension** dans des sens opposés (14, 16) (fig. 1)
   - à des extrémités respectives de la région chauffée
   - afin d'**étirer** cette région chauffée
   - à un diamètre et une épaisseur de paroi plus faibles (A, B) (fig. 1a)(19)(fig. 1b)
   - obtenant ainsi
   - une **préforme tubulaire** (fig. 1c)
   - présentant, à ladite extrémité de ladite partie du tube,
   - une **région effilée** de relativement **faible diamètre**
   - formée d'un matériau
   - ne présentant essentiellement aucune cristallisation ni orientation moléculaire,
   - l'étape consistant à **préformer** cette région d'extrémité effilée
   - permettant à la section correspondante du ballonnet soufflé (fig. 3) d'avoir un profil d'épaisseur séparément contrôlable (fig.3a).

2. Le procédé de la revendication 1, *caractérisé en ce que*
   - on chauffe sélectivement à la température d'étirage
   - **deux régions prédéfinies** (10b) du tube (10) (fig. 1c, 2) et
   - on applique la tension dans des sens opposés à des extrémités respectives de cette région chauffée afin d'étirer **chaque** région à un diamètre et une épaisseur de paroi plus faibles.

3. Procédé selon la revendication 1 ou 2, *caractérisé en ce que*
   - ladite température d'étirage se situe
   - au-dessus de la température de transition vitreuse et
   - au-dessous de la température de cristallisation
   - de manière que n'apparaisse essentiellement aucune cristallisation ni orientation moléculaire.

4. Procédé selon la revendication 1 ou 2, *caractérisé en ce que*
   - ladite température d'étirage se situe
   - au voisinage ou au-dessus de la température de fusion de ladite résine et en ce

que
- après tirage, on trempe rapidement ladite préforme.

5. Procédé selon la revendication 1 ou 2, *caractérisé en ce que*
- ladite température de soufflage se situe
- approximativement à la température de transition vitreuse ou au-dessus de celle-ci, et
- essentiellement au-dessous de la température de cristallisation de ladite résine.

6. Procédé selon la revendication 5, *caractérisé en ce que,*
- pour orienter biaxialement le ballonnet (21),
- ladite température de soufflage se situe
- au-dessous de la température d'étirage
- dans la région de la température de transition vitreuse de ladite résine.

7. Procédé selon la revendication 1 ou 2, *caractérisé en ce que*
- ladite résine est un poly(téréphtalate d'éthylène)amorphe,
- ladite température d'étirage est comprise
- entre environ 105 et 130 °C,
- ladite température de soufflage est comprise
- entre environ 85 et 115 °C.

8. Procédé selon la revendication 1 ou 2, *caractérisé en ce que*
- l'étirage permettant de fabriquer ladite préforme et
- ladite étape d'étirage et de soufflage de cette préforme
- sont en rapport entre eux de manière que
- l'épaisseur de paroi du corps principal du ballonnet (21) et
- l'épaisseur de paroi d'une section d'extrémité effilée de ce ballonnet (21)
- soient de valeur essentiellement égale.

9. Procédé selon la revendication 1 ou 2, *caractérisé en ce que*
- le chauffage de ladite région prédéfinie
- est exécuté d'une manière telle
- que la partie du tube à partir de laquelle doit être formé le corps principal du ballonnet
- ne soit pas essentiellement chauffée.

10. **Produit constitué par le ballonnet** réalisé conformément au procédé de la revendication 1 ou 2.

11. **Produit constitué par le ballonnet** réalisé conformément au procédé de la revendication 8.

12. **Cathéter à ballonnet à dilatation** pour angioplastie
- comportant :
- un **cathéter** allongé de petit diamètre (23)
- conçu pour être introduit dans le système vasculaire du corps
- jusqu'à un point d'occlusion sténotique d'un vaisseau sanguin,
- un **ballonnet** gonflable de **dilatation** - (21)
- fixé autour de ce cathéter (23),
- conçu pour être gonflé audit point d'occlusion
- de manière à agrandir le vaisseau sanguin et supprimer la réduction de débit sanguin, et
- comprenant
- une **section formant corps principal** et
- au moins une **section de transition** à l'une des extrémités de cette section formant corps principal, et
- des **moyens** (25) pour **gonfler** et **dégonfler** le ballonnet (21),

caractérisé en ce que
- le **ballonnet** (21) est
- le produit du processus
- de soufflage et d'étirage
- **d'un organe tubulaire préformé**
- présentant
- un contour effilé
- dans la région correspondant à la région de transition du ballonnet soufflé,
- ce contour effilé
- présentant
- un diamètre plus faible et une épaisseur de paroi réduite
- par rapport au diamètre et à l'épaisseur de paroi de la section formant corps principal,
- permettant ainsi aux sections correspondantes du ballonnet soufflé
- de présenter des profils d'épaisseur séparément contrôlables (fig. 3).

13. Cathéter à dilatation à ballonnet de la revendication 12, *caractérisé en ce que*
- l'organe tubulaire préformé est
- le produit du chauffage et de l'étirement
- d'une région prédéfinie d'un tube extrudé (10)

- de diamètre et d'épaisseur de paroi originels constants.

14. Cathéter à dilatation à ballonnet de la revendication 12,
caractérisé en ce que
- l'épaisseur de paroi de la section de transition effilée est
- à peu près la **même** que l'epaisseur de paroi du corps principal du ballonnet (21).

15. Cathéter à dilatation à ballonnet de la revendication 12,
caractérisé en ce que
- l'épaisseur de paroi de la section de transition effilée est
- moindre que l'épaisseur de paroi du corps principal du ballonnet (21).

16. Cathéter à dilatation à ballonnet de la revendication 12, 13, 14 ou 15,
caractérisé en ce que
- le corps principal du ballonnet (21) présente
- un diamètre gonflé de 5 mm ou plus.

17. Cathéter à dilatation à ballonnet de la revendication 12, 13, 14 ou 15,
caractérisé en ce que
- la résine à partir de laquelle est formé le ballonnet (21) est
- un poly(téréphtalate d'éthylène).

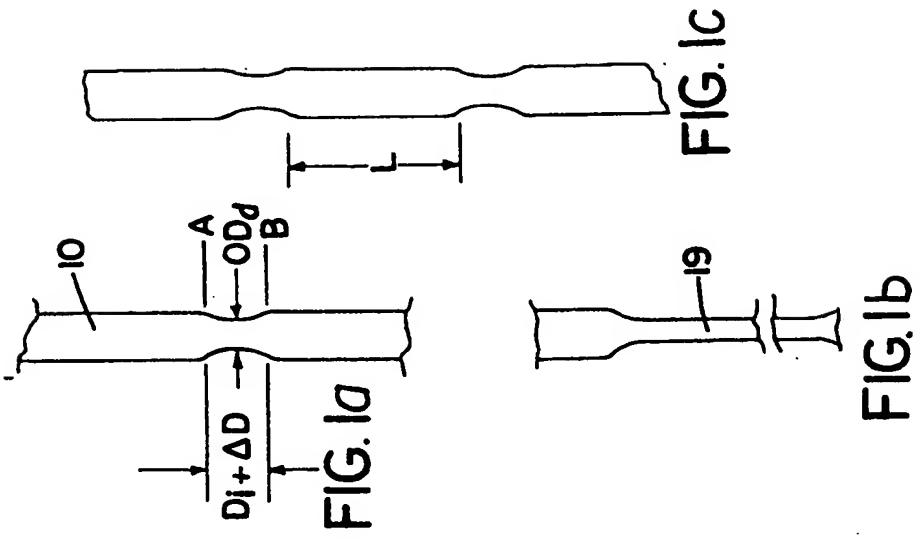
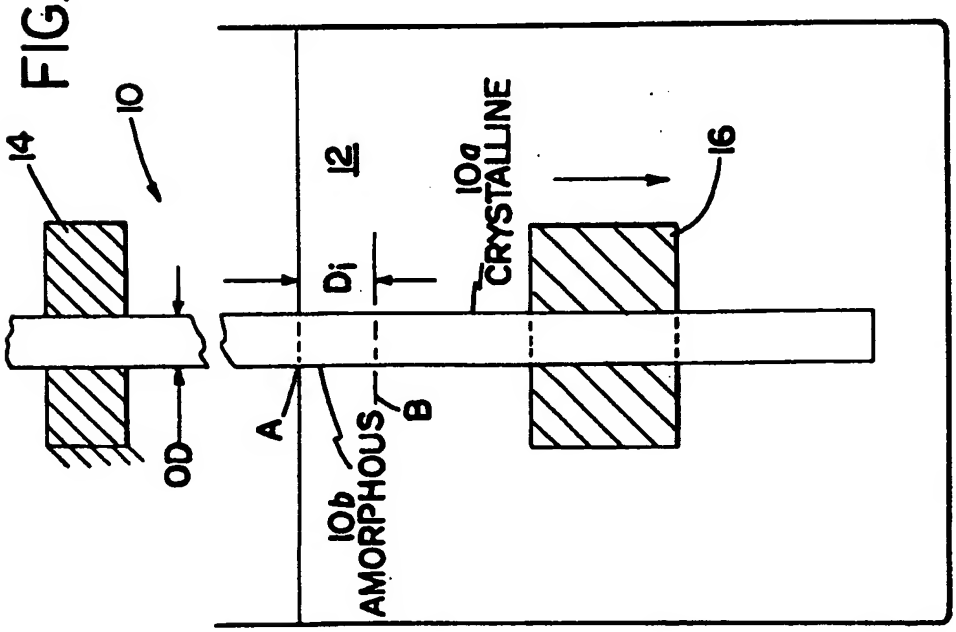


FIG. 1c

FIG. 1a

FIG. 1b

FIG. 1



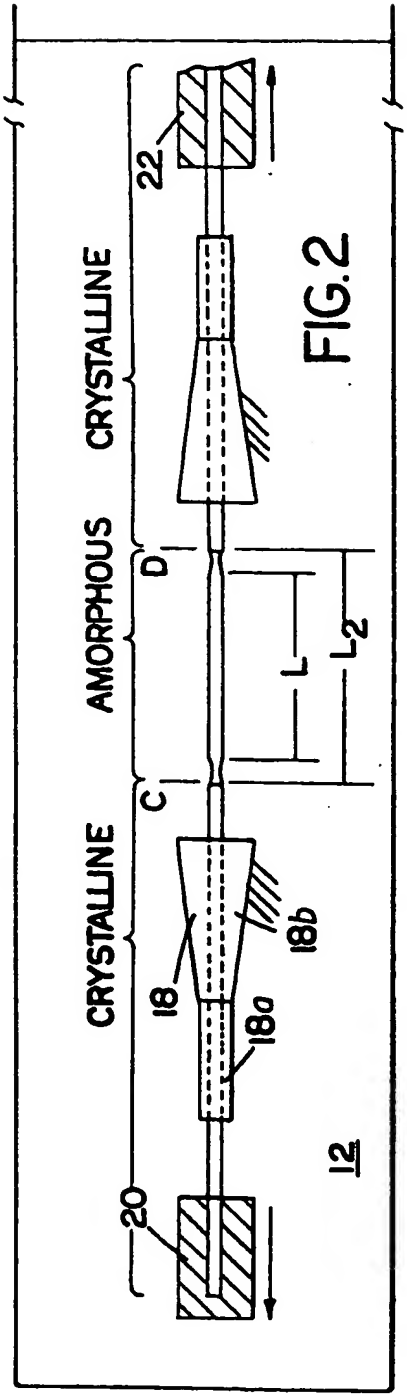


FIG.2

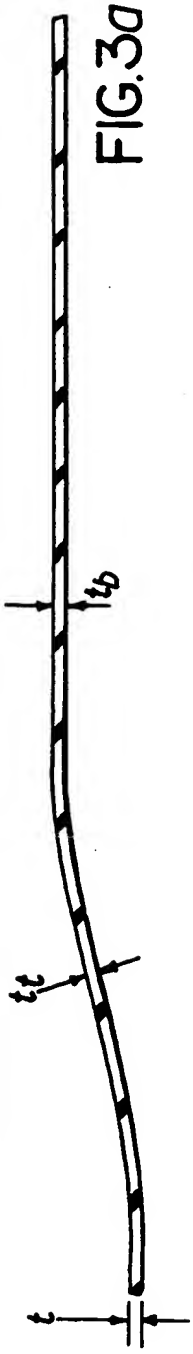


FIG.3a

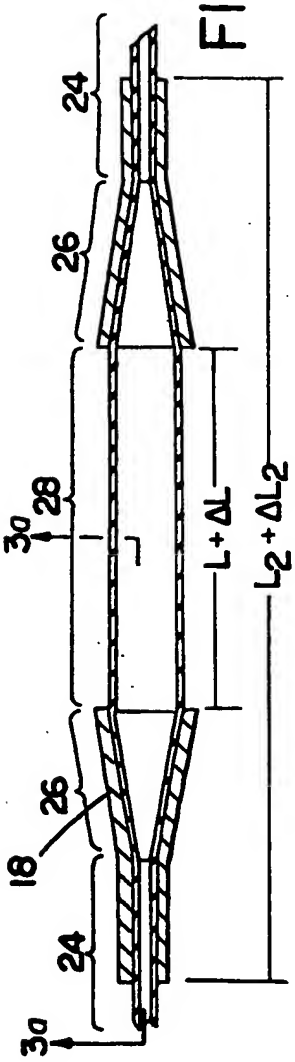


FIG.3

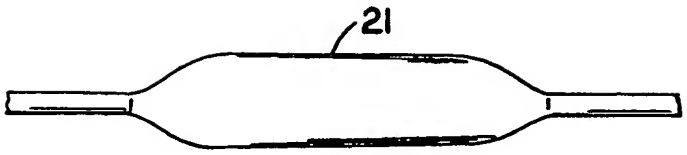


FIG.4

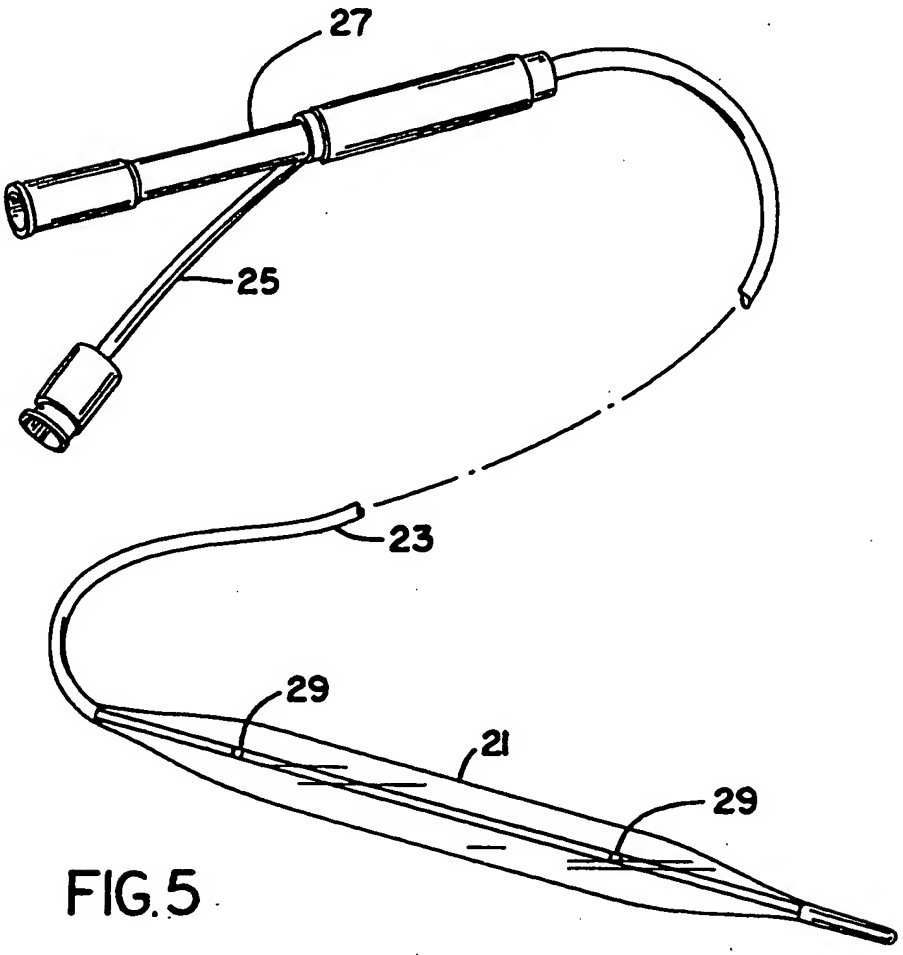
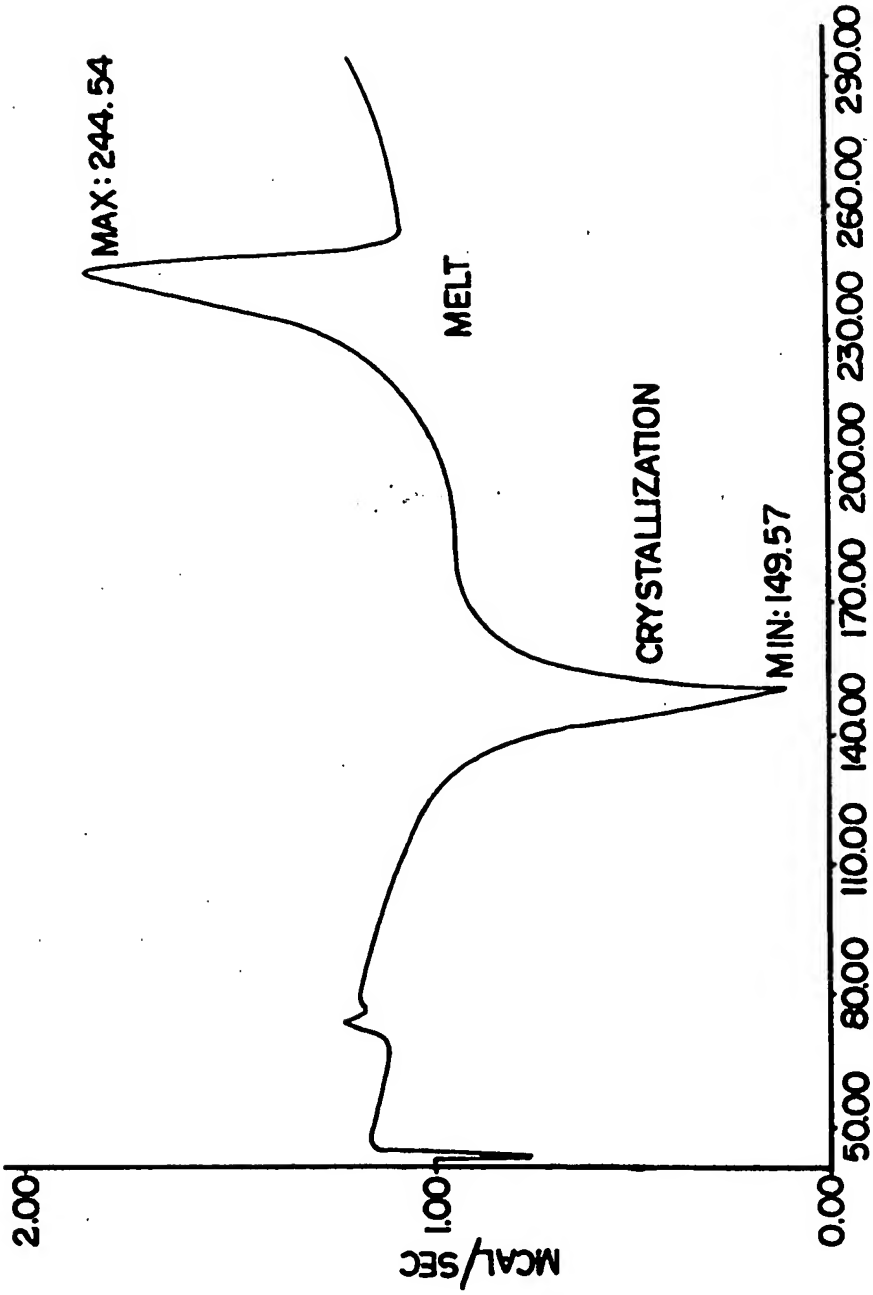


FIG.5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MCAL/SEC
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0.00
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110.00
140.00
170.00
200.00
230.00
260.00
290.00
TEMPERATURE (C)

FIG. 6